

### **REMARKS**

Claims 16-28 and 31 remain pending. In support of the remarks herein, Applicants submit a Declaration under 37 CFR §1.132 from one of the inventors, Dr. Mario Pablo Estrada. In view of the remarks and 132 Declaration submitted herein, reconsideration is respectfully requested.

The claims remain rejected under 35 U.S.C. §103(a) as being obvious over Hipskind et al. (US 5,773,441). In the Office Action, the examiner acknowledges Applicants' arguments that the claimed method for stimulating resistance to disease in fish is not disclosed. However, the examiner asserts that Hipskind teaches that GHRP-6 has a prophylactic effect on disease. The examiner also asserts that Hipskind teaches treatment of fish. Therefore, the examiner concludes that Hipskind teaches or at least suggests that GHRP-6 has a disease-treating effect on mammals, including fish. Applicants respectfully traverse.

At column 3, lines 60-63 of Hipskind, the patentees state, "The compounds employed in the present invention are preferred for human pharmaceutical uses as well as veterinary uses, particularly in cattle, swine, sheep, poultry and fish." Based on the information preceding this disclosure, it is clear that the "compounds" being referred to in Hipskind are the nonpeptidyl analogues disclosed in Hipskind, and not GHRP-6.

The examiner also relies upon the disclosure in Hipskind at column 42, line 64 that the growth hormone secretagogues of the invention can be used in combination with GHRP-6. The examiner then cites column 43 of Hipskind for the disclosure that growth hormone can stimulate the immune system. However, there is no indication in Hipskind that this description of the effects or uses of growth hormone would be effective in fish. As stated above, the only disclosure in Hipskind relating to fish is in column 3, line 64, which relate to the secretagogues

of the invention. As explained in the 132 Declaration attached hereto, this reference to fish in column 3 in connection with the secretagogues of the invention cannot be used to link the disclosure in column 43 of the stimulation of the immune system of mammals using growth hormone because, at the time the Hipskind application was filed, there was no evidence at all in the art that GHRP-6 could be used on fish.

At the time the Hipskind application was filed in 1996, it was not known that a receptor for GHRP-6 was present in fish. Therefore, the general disclosure in column 43 of Hipskind regarding the stimulation of the immune system by growth hormone in mammals should not be linked to the use of the secretagogues in fish as disclosed in column 3.

Furthermore, as set forth in the 132 Declaration, it should be noted that there is a distinction between the “prophylactic use” of GHRP-6 according to the present invention through “stimulation of resistance to diseases” in fish and crustaceans, and the “therapeutic use” of a totally different group of secretagogues (the 2-acylaminopropanamides) as disclosed in Hipskind. As set forth in MPEP §2143, when relying on a rationale for obviousness that includes combining prior art elements or substitution of one known element for another, it must yield a predictable result. As stated by Dr. Estrada in paragraph 16 of his Declaration, a potential therapy based on 2- acylaminopropanamides as disclosed in Hipskind can provide no prediction for efficacy of a similar therapy based on GHRP-6.

In view of the foregoing, withdrawal of the rejection under 35 U.S.C. §103(a) is respectively requested.

Applicants respectfully request that the application is in all respects complete and is in condition for examination and favorable consideration, which actions are earnestly solicited. If the examiner has any questions concerning any aspect of this application, it is respectfully

Applicants: Estrada Garcia, et al.  
September 4, 2008  
Our Docket: 294-194 PCT/US/RCE  
Response to Office Action dated July 22, 2009  
Page 6 of 6

requested that the examiner contact Applicants' attorney at the telephone number provided below.

Respectfully submitted,

/james f. harrington/  
James F. Harrington  
Registration No.: 44,741  
Attorney for Applicant(s)

HOFFMANN & BARON, LLP  
6900 Jericho Turnpike  
Syosset, New York 11791  
(516) 822-3550  
JFH/jp